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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | | |
|-----------------|----------------|------|
| Application No. | 09/210,031 | |
| Examiner | LORINCZ ET AL. | |
| Stephen C Siu | Art Unit | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1) Responsive to communication(s) filed on _____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) 1-27 is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claims ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are objected to by the Examiner.
11) The proposed drawing correction filed on ____ is: a) approved b) disapproved.
12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
1. received.
2. received in Application No. (Series Code / Serial Number) _____.
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) Notice of References Cited (PTO-892) 17) Interview Summary (PTO-413) Paper No(s). _____.
15) Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) Notice of Informal Patent Application (PTO-152)
16) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-8. 19) Other: _____

Art Unit: 1631

DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Information Disclosure Statement

The information disclosure statement filed June 7, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In particular, DE 44 45 769 C1 is not present, therefore the information referred to in regards to reference DE 44 45 769 C1 has not been considered.

Claim Objections

Claims 5, 15-17, 20, and 21 are objected to because of the following informalities: missing commas. The objection would be overcome by insertion of commas after "DNA" in claims 5, 15, 16, 20 and 24 and after "o-phenanthroline" in claim 17.

Claim Rejections - 35 USC § 112

Art Unit: 1631

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 21 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "less than" X "ml" which is confusing because it is not clear what the lower limit of volume is (i.e., 0 ml may be included in the invention). For purposes of examination, a lower limit greater than 0 ml was assumed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-20 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber (WO 94/02645, 3 Feb 1994).

The claims are drawn to a medium containing a cross-linking agent, an anti-degradation agent and a preservative for directly analyzing cells or tissue by cytological and molecular methods.

Weber (WO 94/02645, 3 Feb 1994) discloses a detection method for biopolymers in stained specimens. In the procedure of the invention, a fixative is used to fix cells.

Art Unit: 1631

The fixative is a combination of precipitating fixatives (alcohols) and cross-linking fixatives (aldehydes). The fixative comprises ethanol, ethanol-acetic acid, methanol or methanol-acetone to provide good preservation of cellular morphology and preservation and accessibility of antigens and high hybridization efficiency (page 8, lines 8-29). Simultaneously, the fixative contains glutaraldehyde or formaldehyde which fixes the cellular components by cross-linking materials together (page 9, lines 24-26). In one embodiment, the solution contains guanidinium isothiocyanate, formamide, PEG, DTT, Ficoll/PVP, EDTA, salmon sperm DNA, Tris-acetate and Triton X-100 (page 20, lines 3-10). The procedure allows simultaneous detection of different substances (mRNAs, DNAs and proteins) within the same cells (page 19, lines 13-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber in view of Hurley.

The claims are drawn to a medium containing a cross-linking agent, an anti-degradation agent and a preservative for directly analyzing cells or tissue by cytological

Art Unit: 1631

and molecular methods. The buffer component has a buffering capacity within a pH range of about 3.5 to about 4.5.

Weber (WO 94/02645, 3 Feb 1994) discloses a detection method for biopolymers in stained specimens. In the procedure of the invention, a fixative is used to fix cells. The fixative is a combination of precipitating fixatives (alcohols) and cross-linking fixatives (aldehydes). The fixative comprises ethanol, ethanol-acetic acid, methanol or methanol-acetone to provide good preservation of cellular morphology and preservation and accessibility of antigens and high hybridization efficiency (page 8, lines 8-29). Simultaneously, the fixative contains glutaraldehyde or formaldehyde which fixes the cellular components by cross-linking materials together (page 9, lines 24-26). In one embodiment, the solution contains guanidinium isothiocyanate, formamide, PEG, DTT, Ficoll/PVP, EDTA, salmon sperm DNA, Tris-acetate and Triton X-100 (page 20, lines 3-10). The procedure allows simultaneous detection of different substances (mRNAs, DNAs and proteins) within the same cells (page 19, lines 13-15).

Weber does not explicitly state a pH range for the buffer component.

Hurley (US Pat No. 5,256,571, 10/26/93) discloses a cell preservative solution containing an alcohol selected from the group consisting of ethanol and methanol, a chelating agent selected from the group consisting of EDTA and its salts, and a buffering agent to maintain the pH at from about 4 to about 7 for the duration of the preservation (col.2, lines 15-36).

Art Unit: 1631

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of analysis of cells or tissues using a medium containing a buffer, a preservative, a cross-linking agent and an anti-degradation agent as per the teachings of Weber and to further specify an effective pH range of about 4 because preserving the pH at about 4 for the duration of the preservation would result in effective preservation of the specimen, as per the teachings of Hurley. Therefore, one of ordinary skill in the art would have been motivated to buffer the solution with a buffer at a pH of about 4 with a reasonable expectation of success.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber in view of Wainwright (US Pat No. 5,370,128, 12/06/94).

The claims are drawn to an article of manufacture comprising a container with a lid holding a medium and a cell collecting device having an elongated member with a brush, the container holding less than 2 ml of the recited medium.

Weber discloses the medium as described above.

Weber does not disclose a container with a lid and elongated member holding the medium.

Wainwright (US Pat No. 5,370,128, 12/06/94) discloses a pap brush and pap unit container system for preserving a cell sample and comprising a pap unit having side walls and a bottom wall forming a well and a lid coupled with respect to the upper ends of the side walls to seal therein the fluid and brush containing the pap samples. The pap

Art Unit: 1631

brush has a long handle and bristle support member and a plurality of bristles extending parallel with the handle along the end of the support member remote from the handle (see abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of analysis of cells or tissues using a medium containing a buffer, a preservative, a cross-linking agent and an anti-degradation agent as per the teachings of Weber and to further incorporate the medium in a container system designed for preserving cell samples and comprising a container with a lid and elongated member or brush as per the teachings of Wainwright. The container and brush apparatus was disclosed by Wainwright as having useful applications in preserving cell samples from pap smears. One of ordinary skill in the art would have been thus motivated to place a medium for preserving cell samples within the container device and would have utilized the cell preservation medium of Weber in the container system of Wainwright with a reasonable expectation of success.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522

Art Unit: 1631

before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu

03/09/00



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER